Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2017722	09/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Alliance Dermatology	313 S Beeline Hwy, Payson, AZ	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for review and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the sub-specialty of Histopathology at least twice annually during 2018. Findings include: 1. No documentation was presented for review during the survey to indicate that the laboratory verified the accuracy of Mohs testing at least twice annually during 2018. 2. The facility personnel confirmed that the laboratory failed to verify the accuracy of Mohs testing at least twice annually during 2018.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to document the acceptability of staining materials used for testing performed in the sub-specialty of histopathology. Findings include: 1. The laboratory performs patient testing under the sub-specialty of Histopathology

	with an approximate annual test volume of 3,247. 2. No documentation of the H & E stain acceptability was presented for review for testing that occurred on 06/25/2019. The number of patients tested that date could not be determined at the time of the survey. 3. The facility personnel confirmed that the laboratory failed to document the H & E stain acceptability on the date indicated above.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of corrective action presented for review and interview with the facility personnel, the laboratory failed to document corrective actions taken for room temperature measurements that were outside the laboratory's established range. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Histopathology, with an approximate annual test volume of 3,247. The laboratory's established room temperature range is 70-82 degrees Fahrenheit. 2. Review of laboratory temperature logs for 2019 indicated that the room temperature was above the acceptable range for several days throughout the year, from January to the date of the survey conducted on September 20, 2019. 3. No corrective action documentation was presented for review for the out of range room temperature measurements, to indicate the laboratory resolved the problem and the steps taken to prevent reoccurrence of the problem. 4. The facility personnel confirmed that the laboratory did not document any corrective actions for the room temperature measurements that were outside the laboratory's established range.